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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,209	04/20/2006	Julie Hazel Campbell	4501-1016	9620

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EXAMINER	
TSAY, MARSHA M	

ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,209	CAMPBELL ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-16 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 07/25/05; 07/05/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-16 are pending and currently under examination.

Priority: The benefit date is October 4, 2002 for the purpose of prior art.

Specification

The disclosure is objected to because of the following informalities: on page 1 of the specification, the priority data needs to be updated by a cross-reference paragraph to related applications.

Appropriate correction is required.

Claim Objections

Claim 8 is objected to because of the following informalities: in claim 8, line 3, the term "of" should be corrected to "from". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 13 provides for the use of β-casein A^2, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 13 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a method of reducing the serum level in a mammal of any one or more of the following: (a) to (f). It is unclear if the elements recited in (a) to (f) are or can be reduced simultaneously and which other combinations of (a) to (f) can be reduced. Also, it is unclear how element (b) is different over element (c); reducing LDL cholesterol relative to HDL cholesterol (as recited in 1b) appears to be the same as just reducing LDL cholesterol (as recited in 1c). The claim also contains some grammatical errors which can be remedied by amending the claim language. A proposed amendment to claim 1 follows: A method of reducing serum levels of any one or more of the following: (a) to (f) in a mammal comprising orally administering to said mammal a composition comprising β-casein where the β-casein is comprised of at least 95% β-casein A^2.

In claim 3, the acronym LDL needs to be defined in full upon its first appearance in the claims for clarity. Further, claim 3 is generally narrative and indefinite, failing to conform with current U.S. practice. It contains grammatical and idiomatic errors.

Claim 4 should be written in proper Markush language. The claim should recite: A method as claimed in claim 3 where the disease or disorder is selected from the group consisting of hypercholesterolemia, hyperlipidemia, and atherosclerosis.

Claim 8, as currently written, is confusing. The claim should recite: A method as claimed in claim 7, where the dietary supplement \is ingested for optimizing fitness, weight loss, weight gain, muscle building, and/or muscle repair.

Claim 11 is generally narrative and indefinite, failing to conform with current U.S. practice. It contains grammatical and idiomatic errors. It is unclear if Claim 11 means to recite: The method according to claim 1, where the mammal is human.

Claims 15-16 recite the limitation "a dietary supplement" in the claims. There is insufficient antecedent basis for this limitation in the claims or their parent claim. It appears the claims should be dependent on claim 14 and not on claim 13 (as is currently recited).

Claims 2, 5-7, 9-10, 12, 13-14 are included in this rejection because they are dependent on claim 1 and fail to cure its defect.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14-16 are rejected under 35 U.S.C. 102(a) as being anticipated by Beales et al. (2002 Diabetologia 45(9): 1240-1246; IDS). Beales et al. teach a dietary supplement of Pregestimil (PG, a hydrolysed casein based formula p. 1241) plus 10% casein containing only the β-casein A^2 (p. 1242 col. 1; claims 14-16).

Claims 13-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Elliott et al. (US 6451638). In Example 3, Elliott et al. teach a supplement of Prosobee plus 10% Bos indicus casein (col. 7 table 4; claims 14-16). Elliott et al. further teach that Bos indicus casein was found to contain only the β-casein A^2 variant (col. 9 lines 49-50; claims 14-16). In Example 7, Elliott et al. teach β-casein A^2 was purified and used for the manufacture of a casein milk product (col. 9 lines 49-68; claim 13).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elliott et al. (WO 0100047; IDS). Elliott et al. disclose a method for reducing the incidence of cardiovascular disease and peripheral vascular disease comprising the steps of manufacturing and administering a dietary supplement in the form of a milk product including A^2 β-casein but substantially no A1 or B β-casein (p. 10-11 lines 307-311). Elliott et al. also disclose that both Type I and Type 2 diabetes increase the risk of coronary heart disease (p. 20 lines 577-578). In Experiment 1, Elliott et al. disclose the administration of Prosobee (soy preparation used as rat food) plus 10% type A^2 β-casein to study the incidence of diabetes (p. 13-14 lines 389-406; claims 1-11). Elliott et al. disclose the β-casein A^2 can be obtained from *Bos indicus*, Icelandic dairy cows, goats (p. 23 lines 665-667; claim 12). Elliott et al. disclose food products made from type A^2 β-casein, including yogurt, cheese, wherein the β-casein A^2 can be fortified with additional compounds (p. 22 lines 637-655; claims 8, 13-16). Elliott et al. do not explicitly teach the oral administration of β-casein A^2 to a mammal for reducing cholesterol.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to orally administer the β-casein A^2 supplement of Elliott et al. to a patient for reducing cardiovascular disease and associated conditions, such as high cholesterol because Elliott et al. disclose a milk product comprising solely of β-casein A^2 can be manufactured and administered as a dietary supplement for reducing cardiovascular disease and peripheral vascular disease (claims 1-16).

While Elliott et al. do not explicitly teach the elements of reducing cholesterol, apolipoprotein B, triglycerides, hypercholesterolemia, hyperlipidemia, atherosclerosis or that said β-casein is at least 95% β-casein A^2, these elements are believed to be unpatentable over

Elliott et al. because Elliott et al. disclose the supplement comprises β-casein A^2 but substantially no A1 or B β-casein. Therefore, one of ordinary skill would recognize that the β-casein of Elliott et al. comprises solely of β-casein A^2 and at least 95% β-casein A^2. Regarding the elements of reducing cholesterol, apolipoprotein, triglycerides, hypercholesterolemia, hyperlipidemia, and atherosclerosis, one of ordinary skill would recognize that these are factors that are strongly correlated with an increased risk of heart disease, and are unpatentable over Elliott et al. because Elliott et al. disclose a method for reducing the incidence of cardiovascular disease by administering β-casein A^2; and therefore, it would be reasonable to expect that said elements would be reduced upon administration of β-casein A^2 into a patient.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

August 29, 2007

M. Monshipouri
MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER